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09/771,383	01/25/2001	Kevin Delos Parris	2368/12	6452

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[REDACTED] EXAMINER

LY, CHEYNE D

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1631

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14

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/771,383	Applicant(s) PARRIS ET AL.
	Examiner Cheyne D Ly	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on March 03, 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 15-22 and 35-84 is/are pending in the application.

4a) Of the above claim(s) 18 and 22 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 15-17, 19-21 and 35-84 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 15-22 and 35-84 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicants' arguments in Paper No. 13, filed March 03, 2003, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. It is acknowledged that claims 1-14 and 23-34 have been cancelled; and new claims 35-84 have been added.
3. Claims 15-17, 19-21, and 35-84 are examined on the merits.

**CLAIMS OBJECTIONS**

4. The title of the invention is not descriptive because the claimed invention is directed to a method for identifying an agent that interacts with an ACPS active site while the title is directed to crystal structure of the ACPS. A new title is required that is clearly indicative of the invention to which the claims are directed.
5. Claims 15, 19, 35, 68, 71, and 74, step (b), are objected to because of the following informalities: The conjunction "and" is needed between the phrases "in step (b)" and "+/- a root mean square". Appropriate correction is required.

**CLAIM REJECTIONS - 35 U.S.C. § 112**

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 15-17, 19-21, and 35-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention. This rejection is necessitated by Applicants amendments.

8. Specific to claims 15, 19, 35, 68, 71, and 74, steps (b) and (c), the phrase "relative structural coordinates" causes the claims to be vague and indefinite. The limitations of obtaining and using the relative structural coordinates are unclear because it is unclear how the structural coordinates are related to each other (position of amino acids, atomic distance, or degree of affinity to an agent). Clarification of the metes and bounds is required. Claims 16, 17, 20, 21, 36-67, 69, 70, 72, 73, and 75-84 are rejected for being directly or indirectly dependent from claims 15, 19, 35, 68, 71, and 74.

**LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 15-17, 19-21, and 35-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a crystal structure of ACPS and ACPS-CoA complex ACPS cloned and isolated from *B. subtilis* (Page 11, lines 8-10) and which have atom coordinates instantly disclosed (Figures 1-2A-19), does not reasonably provide enablement for a method for identifying an agent that interacts with an active site of ACPS or any ACPS-CoA complex cloned and isolated from any other organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

11. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

12. It is acknowledged that the applicant has disclosed information to enable one skilled in the art to make a specific crystal of the ACPS and ACPS-CoA complex cloned and isolated from *B. subtilis* (Page 11, lines 8-10). Applicant disclosed that molecular modeling methods known in the art may be used to identify an active site of the ACPS molecule or ACPS molecular complex (Page 15, Lines 1-2). However, a method that relies on data from an unpredictable art such as protein crystallization would require clear and precise guidance for one skilled in the art to reliably use the said method. It is well documented that protein crystallization is in essence a trial-and-error method, and the results are usually unpredictable (Drenth, J.). Further, as recently as November 1, 2002, *Science* published a New Focus article depicting the current state of the art for protein crystallization that supports the unpredictability of the art. In essence, protein crystallization is still a trial and error process

because the current technology for producing protein for the crystallization process is unpredictable, which results in high failure rate for proteins that are being crystallized. Therefore, researchers continue to have trouble generating sufficient protein required for the crystallization process (New Focus, Science, 2002). Accordingly, it would be unpredictable for one skilled in the art to make crystal structures of other ACPS or ACPS-CoA proteins or complexes beyond the ones of the instant case where specific coordinates are disclosed. In light of the difficulty of the protein crystallization process, it is, therefore, unreasonable to expect one skilled in the art to use the information disclosed for one specific crystal to make other of predictable quality that are cloned and isolated from any other organism without undue experimentation.

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the

time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 15-17, 19-21, and 35-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosowsky et al. (1999) in view of In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) taken with Ahern (The Scientist, 1996). This rejection is maintained with respect to claims 15-17 and 19-21, as recited in the previous office action Paper No. 12, mailed December 03, 2002. Further, this rejection is hereby extended to newly added claims 35-84.
2. It is acknowledged that Applicants amended claims 15-17 and 19-21 by adding limitations directed to crystal structure information. Further, Applicants added new claims 35-84 that have limitations that are directed to crystal structure information. It is re-iterated that the specific limitations of crystal structure coordinates and the three-dimensional model of ACPS in this instant case do not distinguish the invention from the prior art in term of patentability because they are descriptive nonfunctional subject matter.

#### **CONCLUSION**

#### **15. NO CLAIM IS ALLOWED.**

16. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.
18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.
19. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly  
5/13/03

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER